UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

CHRISTOPHER THORPE and LAURE THORPE,	:	CA 08 463 ML
Plaintiffs,	:	
vs.	:	**Civil Action No:**
DAVOL INC. and C. R. BARD INC.,	:	
Defendants.	:	

COMPLAINT

Parties

1. Plaintiff, CHRISTOPHER THORPE ("Mr. THORPE") is a citizen and resident of the County of Catawba, State of North Carolina.

2. Plaintiff, LAURE THORPE is a citizen and resident of the County of Catawba, State of North Carolina. At all times relevant hereto, Plaintiff is and was the lawful spouse of CHRISTOPHER THORPE.

3. Defendant, DAVOL INC. ("DAVOL") is a corporation that is incorporated under the laws of the State of Rhode Island. DAVOL has its principal place of business in the State of Rhode Island. It manufactures the Composix® Kugel Mesh Patches ("Kugel Patch") at 100 Sockanosset Crossroad, Cranston, Rhode Island. DAVOL focuses its business on products in key surgical specialties, including hernia repair, hemostasis, orthopedics, and laparoscopy. DAVOL at all times relevant did substantial and continuous business in the States of Rhode Island and North Carolina.

4. Defendant, C. R. BARD INC. ("BARD") is a corporation that is incorporated under

the laws of the State of New Jersey. It is the corporate parent/stockholder of DAVOL and participates in the manufacture and distribution of the Kugel Patch. It also manufactures and supplies DAVOL with material that forms part of the Kugel Patch. BARD at all times relevant did substantial and continuous business in the States of Rhode Island and North Carolina.

Jurisdiction

5. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000.00 exclusive of interest and costs, and because this is an action by an individual Plaintiff who is a citizen of a different state from the Defendant.

6. Venue is proper in this District pursuant to 28 U.S.C. § 1391. Defendants are located in this District, manufactured and advertised the subject Kugel Composix Hernia Patches in this District, received substantial compensation and profits from sales of Kugel Composix Hernia Patches in this District, and/or made material omissions and misrepresentations and breached warranties in this District.

Facts

7. Defendant DAVOL designed, manufactured and distributed the Composix Kugel Patch, a hernia mesh patch that was inserted into Mr. THORPE's body.

8. Defendant DAVOL, through its agents, servants and employees, participated in the manufacture and delivery of the Composix Kugel Patch that was inserted into Mr. THORPE's body.

9. The Defendants submitted their 510k Application to the Federal Drug Administration (hereinafter referred to as the "FDA") on January 22, 2001. Following this 510k Application the Composix Kugel Patch was authorized by the FDA as a Class II medical device.

10. Immediately after the Kugel Patches were placed on the market, DAVOL and BARD began receiving actual notices of memory ring failures and Kugel Patch defects. DAVOL and BARD actively and intentionally concealed this notice of the defective and dangerous condition associated with the Kugel Patches from Mr. THORPE, Plaintiff's physicians, and the general public.

11. After the defective and dangerous Kugel Patch was already placed on the market, Defendants DAVOL and BARD conducted physician screenings and reviews as early as 2002. An Establishment Inspection Report ("EIR") conducted by the FDA in 2006 found that the post market survey validation process of the device was incomplete and failed to include all the data from the physicians surveyed during this time. Whether intentionally or negligently, BARD and DAVOL failed to properly conduct and monitor their own post market design validation physician surveys including those which demonstrated unfavorable or "dissatisfied" results. These complaints and concerns of the physician surveyors were actively concealed by DAVOL and BARD from Mr. THORPE, Plaintiff's surgeons, and the public at large.

12. On November 17, 2005, Mr. THORPE had a ventral hernia repaired at the Frye Regional Medical Center in Hickory, North Carolina. An Extra-Large Oval Composix Kugel Patch was implanted into Mr. THORPE at this time.

13. The Composix Kugel Patch hernia repair product implanted in Mr. THORPE was designed, manufactured, sold and distributed by DAVOL to be used by surgeons for hernia repair surgeries and was further represented by DAVOL to be an appropriate, cost-effective and suitable product for such purpose.

14. No later than September 2004, Defendants uncovered serious problems with the weld process involving the memory recoil ring. Despite attempts to correct the problem at the plant,

BARD and DAVOL found the corrective measures to be ineffective and the process still not in control. DAVOL and BARD were ware these weld issues had existed from the time the Kugel Patches were originally placed on the market and all current lots suffered from this dangerous defect. This information was intentionally withheld at this time from Mr. THORPE, Plaintiff's physicians, the FDA, and all other individuals who had been implanted or would be implanted with Kugel Patches using the memory recoil ring.

15. During the 2006 EIR, corporate executives informed the FDA that the spring and summer period of 2005 showed a marketed increase in the number of complaints with the Kugel Patch and the memory recoil ring. In spite of their knowledge of increasing complaints and complications, DAVOL and BARD waited until August 30, 2005 to initiate a partial Kugel Patch distribution hold. DAVOL and BARD actively and intentionally chose not to immediately inform Mr. THORPE, Plaintiff's physicians, the FDA, and all other individuals who had been implanted or would be implanted with Kugel Patches using the memory recoil ring. DAVOL and BARD waited until December 2005 to notify the public of the potential severity of the complications which were resulting from the dangerous and defective Kugel Patches and have since admitted that the product quality hold and release procedure was not applied on a timely basis.

16. An FDA Class I recall is issued for problems related to medical devices that are potentially life-threatening or could cause a serious risk to the health of the patients implanted with the devices.

17. On December 22, 2005, DAVOL recalled many sizes of Composix Kugel Patches under a Class I recall notice.

18. The Composix Kugel Patch was recalled due to a faulty "memory recoil ring" that can

break under pressure. Incidents of ring migration, intestinal fistulae, bowel perforation and even death have been reported.

19. The FDA conducted the aforementioned EIR investigations in January and February of 2006. The results of these investigations determined, among other things, that BARD and DAVOL:

i. had excluded ring failure events which should have been included from their complication database, reports, and recall notices;
ii. misidentified numerous Kugel Patch complication events;
iii. failed to apply the product quality hold and release procedure on a timely basis;
iv. failed to properly follow the procedures for conducting design validation review;
v. failed to identify all the actions necessary to correct and prevent the recurrence of further ring break and Kugel Patch complications; specifically, they provided no justification for including only the Extra Large Kugel Patch sizes in the December 2005 recall;
vi. failed to provide full information which they knew regarding numerous Kugel Patch complaints;
vii. failed to actually perform strength testing on memory recoil rings for all sizes of Kugel patch before putting them into the stream of commerce;
viii. failed to maintain appropriate sources for quality data to identify, track, and trend existing and potential causes for the ring failures and Kugel Patch complaints resulting in numerous inconsistencies and errors in the raw data and from the actual complaints and what was placed in the electronic databases.

20. On March 24, 2006, the initial Class I recall on the Composix Kugel Patch was expanded to include several more sizes of the patch and numerous additional lots of the defective hernia mesh product.

21. On January 10, 2007, the existing recall on the Composix Kugel Patch was again expanded to encompass further production lots of the defective hernia mesh product.

22. Plaintiff was never informed by Defendants of the defective, dangerous, and recalled nature of the Kugel Patch and memory recoil ring which had been implanted until well after

discovering of Bard's and Davol's FDA recall of the product.

23. Neither Mr. THORPE nor Plaintiff's physicians were aware of the defective and dangerous condition of the Kugel Patch or that this unreasonably defective condition was the cause of Mr. THORPE's injuries until some time after BARD and DAVOL chose to finally inform the general public of the defective nature of the Kugel Patches and the subsequent recalls.

24. Mr. THORPE began suffering from severe abdominal pain and abdominal cramping, and was treated for an abdominal wall abscess in or about October 19, 2007 after further developing a fever and abdominal swelling and redness. After six days of hospitalization, Mr. THORPE was discharged to home care.

25. On October 31, 2007, Mr. THORPE required an additional surgical procedure to again treat the abscess being caused by his Composix Kugel Patch. During this procedure, Mr. THORPE's Patch was debrided and the abscess was drained. Mr. THORPE's surgeons then fashioned a wound vac sponge, sealed it in place, and connected it to suction.

26. By the end of November 2007, Mr. THORPE had developed a fistula from what was later uncovered to be the result of the broken memory recoil ring in his defective Composix Kugel Patch. A plan was implemented by Mr. THORPE's treating physicians for them to monitor and non-surgically treat the fistula to give him time to improve his physical condition before then undergoing an attempted takedown of his fistula through another exploratory laparotomy.

27. On or about February 9, 2008, Mr. THORPE presented to Duke University Medical's Emergency Room with nausea, abdominal pain, and increased yellow-green semi-solid drainage from his hernia repair site. After his pain and condition stabilized, Mr. THORPE was discharged from Duke University Medical on February 14, 2008.

28. On or about April 10, 2008, Mr. THORPE was admitted to Duke University Medical for surgical treatment of the enterocutaneous fistula, excision of his mesh, resection of his bowel, repair of the ventral hernia, adhesiolymis, treatment of his abdominal infection, and placement of a new wound vac. After surgically entering Mr. THORPE's abdomen, it became clear to the surgeons that "the ring that was keeping the mesh extended was absent from the right lateral border of the mesh. In fact, the ring was found to be sticking out into the subcutaneous tissues." The broken memory recoil ring was "bile stained" and removed and it was suspected that Mr. THORPE had become septic. Through further dissection, Mr. THORPE's surgeons also observed that the Composix Kugel Patch "had clearly lost its normal alignment and folded upon itself exposing the rough Marlex surface to the bowel." Mr. THORPE's surgeons spent approximately another 3 ½ hours removing the adhesions of the Composix Kugel Patch to the bowel, resected portion of the bowel, repairing the damage caused by the defective patch, and entirely removing the Composix Kugel Patch components. Due to the soiling and contamination of the abdominal contents because of the bowel perforations, Mr. THORPE could not receive a new mesh repair and was instead irrigated and closed.

29. Mr. THORPE was finally discharged from the hospital on or about April 25, 2008 with an open wound and home treatment and care regiment.

30. Mr. THORPE has suffered and will continue to suffer physical pain and mental anguish.

31. Plaintiffs have incurred substantial medical bills and Mr. THORPE has lost wages.

32. DAVOL and BARD withdrew a large number of Composix Kugel Patches as a result of the high complication and failure rate of the product.

33. Upon information and belief DAVOL and BARD failed to comply with the FDA application and reporting requirements.

34. Upon information and belief DAVOL and BARD were aware of the high degree of complication and failure rate associated with their Composix Kugel Patch before it was recalled.

35. Upon information and belief DAVOL and BARD were aware of the defect in manufacture and design prior to the recall of their Composix Kugel Patch.

36. Upon information and belief, the complications and failures associated with the Composix Kugel Patches and Kugel Patches are not limited to the Composix Kugel Patch sizes which DAVOL and BARD has already recalled.

37. Upon information and belief, DAVOL and BARD were aware of the defect in manufacture and design of the non-recalled Kugel Composix Patch sizes and the Kugel Patches and chose not to issue a recall on all Kugel Patches in the face of the high degree of complication and failure rates.

COUNT I
Negligence

38. Plaintiffs re-allege and incorporate by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

39. Defendants DAVOL and BARD were negligent to Plaintiffs in the following respects:

40. DAVOL and BARD at all times mentioned had a duty to properly manufacture, test, inspect , package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for use the Composix Kugel Patch.

41. DAVOL and BARD at all times mentioned knew or in the exercise of reasonable care

should have known, that the Composix Kugel Patches were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold supplied, prepared and/or provided with the proper warnings, and were unreasonably likely to injure the Composix Kugel Patch's users.

42. DAVOL and BARD so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the Composix Kugel Patch, that they were dangerous and unsafe for the use and purpose for which it was intended.

43. DAVOL and BARD were aware of the probable consequences of the Composix Kugel Patch. DAVOL and BARD knew or should have known the Composix Kugel Patch would cause serious injury; they failed to disclose the known or knowable risks associated with the Composix Kugel Patch. DAVOL and BARD willfully and deliberately failed to avoid those consequences, and in doing so, DAVOL and BARD acted in conscious disregard of the safety of Mr. THORPE.

44. Defendants DAVOL and BARD owed a duty to Mr. THORPE to adequately warn him and his treating physicians, of the risks of breakage, separation, tearing and splitting associated with the Composix Kugel Patch and the resulting harm and risk it would cause patients.

45. Defendants DAVOL and BARD breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Composix Kugel Patch.

46. As a direct and proximate result of the duties breached, the Composix Kugel Patch

used in Mr. THORPE's hernia repair surgery failed, resulting in Mr. THORPE suffering pain and harm.

47. As a direct and proximate result of DAVOL's and BARD's negligence, Mr. THORPE has suffered injuries and damages.

48. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Composix Kugel Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

Wherefore, Plaintiffs respectfully request a judgment against DAVOL and BARD for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT II
Strict Product Liability

49. Plaintiffs re-allege and incorporate by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

50. Defendants DAVOL and BARD are strictly liable to Plaintiffs in the following respects:

51. DAVOL and BARD designed, manufactured, assembled, distributed, conveyed and/or sold the Kugel Patch for hernia repair surgery.

52. The Composix Kugel Patches subject to the Class I recall were defective because they

failed to perform safe and effectively for the purpose they were originally designed. Mr. THORPE's Composix Kugel Patch was a Class I recalled device that failed while in his body causing him to develop serious physical complications which required subsequent, painful and unnecessary removal surgery of his Composix Kugel Patch.

53. At all times mentioned, the Composix Kugel Patch was substantially in the same condition as when it left the possession of DAVOL.

54. The Composix Kugel Patch implanted into Mr. THORPE was being used in a manner reasonably anticipated at the time it was implanted in him by his surgeon.

55. The Composix Kugel Patches, like the one found in Mr. THORPE, at the time they left the possession of DAVOL and BARD were inherently dangerous for their intended use and were unreasonably dangerous products which presented and constituted an unreasonable risk of danger and injury to Mr. THORPE as follows:

i. The Composix Kugel Patch was sold in a defective condition by design and manufacture;
ii. The Composix Kugel Patch as designed and manufactured was unsafe to Mr. THORPE;
iii. The Composix Kugel Patch as designed and manufactured was unreasonably dangerous to Mr. THORPE;
iv. The Composix Kugel Patch did not perform safely as an ordinary consumer/patient, like Mr. THORPE, would expect;
v. The Composix Kugel Patch as designed and manufactured was unsafe for its intended use;
vi. DAVOL and BARD failed to warn the end user about the dangers and risks of the product;
vii. DAVOL and BARD knew the component parts of the Composix Kugel Patch as implemented through design and/or manufacture could cause injury to the end user;
viii. Failing to implement an adequate, safe and effective "memory recoil ring" and/or its interaction with the mesh of the Composix Kugel Patch to withstand the foreseeable stresses they would be subject to within the intra-abdominal space;

ix. Failing to avoid migration of the Composix Kugel Patch and/or its components from the initial site of the hernia repair surgery.

x. Any other acts or failures to act by DAVOL or BARD regarding the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing, and/or sale of Composix Kugel Patches for hernia repair surgery as will be learned during discovery.

56. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Composix Kugel Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

Wherefore, Plaintiffs respectfully request a judgment against DAVOL and BARD for damages in a sum as permitted by statute together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT III
Negligent Infliction of Emotional Distress

57. Plaintiffs re-allege and incorporate by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

58. Defendants DAVOL and BARD are liable to Plaintiffs for the negligent infliction of emotional distress in the following respect:

59. Plaintiffs suffered severe emotional distress, which was as a result of Defendant's negligent conduct in studying, designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting, distributing, and/or selling of the Composix Kugel Patch for hernia repair surgery.

60. Plaintiffs suffered severe emotional distress, which was as a result of DAVOL's and BARD's negligent conduct in failing to adequately and safely design and construct an effective and safe Composix Kugel Patch for hernia repair surgery.

61. Therefore, DAVOL and BARD are liable to Plaintiffs.

62. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Composix Kugel Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

Wherefore, Plaintiffs respectfully request a judgment against DAVOL and BARD for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT IV
Intentional Infliction of Emotional Distress

63. Plaintiffs re-allege and incorporate by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

64. Defendants DAVOL and BARD are liable to Plaintiffs for the intentional infliction of emotional distress in the following respect:

65. Plaintiffs suffered severe emotional distress, which was as a result of DAVOL's and BARD's extreme outrageous, intentional, willful, and reckless conduct in studying, designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting,

distributing, and/or sale of the Composix Kugel Patch for hernia repair surgery.

66. Plaintiffs suffered severe emotional distress, which was as a result of DAVOL's and BARD's extreme outrageous, intentional, willful, and reckless conduct in failing to adequately and safely design and construct an effective and safe Composix Kugel Patch for hernia repair surgery, in complete and reckless disregard of safety to Mr. THORPE.

67. Therefore, DAVOL and BARD are liable to Plaintiffs.

68. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Composix Kugel Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

Wherefore, Plaintiffs respectfully request a judgment against DAVOL and BARD for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT V
Breach of Implied Warranty

69. Plaintiffs re-allege and incorporate by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

70. Defendants DAVOL and BARD are liable to Plaintiffs for their breach of implied warranty in the following respect:

71. DAVOL and BARD sold the Kugel Patch which was implanted in Mr. THORPE.

DAVOL and BARD impliedly warranted to Mr. THORPE, his physicians and health care providers, that the Composix Kugel Patch was of merchantable quality and safe for the use for which they were intended.

72. DAVOL and BARD knew or should have known that the Composix Kugel Patch at the time of sale was intended to be used for the purpose of surgically implanting them into the body for hernia repair.

73. Mr. THORPE, his physicians and health care providers reasonably relied on DAVOL's and BARD's judgment, indications and statements that the Composix Kugel Patch was fit for such use.

74. When the Composix Kugel Patches was distributed into the stream of commerce and sold by DAVOL and BARD, they were unsafe for their intended use, and not of merchantable quality, as warranted by DAVOL and BARD in that they had very dangerous propensities when used as intended and implanted into a patient's body where they could cause serious injury of harm or death to the end user.

75. Mr. THORPE suffered such injuries and damages as a result of DAVOL and BARD's conduct and actions.

Wherefore, Plaintiffs respectfully request judgment in their favor and against DAVOL and BARD for such amount that is determined to be fair and reasonable, for such other relief as may be fair and reasonable under the circumstances and for their costs.

COUNT VI
Failure to Warn

76. Plaintiffs re-allege and incorporate by reference each and every allegation contained

in preceding paragraphs as though fully set forth herein.

77. In the course of business, DAVOL and BARD designed, manufactured and sold the Composix Kugel Patch for hernia repair surgeries.

78. At the time of the design, manufacture and sale of the Composix Kugel Patch, and more specifically at the time Mr. THORPE received the Composix Kugel Patch, they were defective and unreasonably dangerous when put to their intended and reasonably anticipated use. Further the Composix Kugel Patches were not accompanied by proper warnings regarding significant adverse consequences associated with the Composix Kugel Patch.

79. BARD and DAVOL failed to provide any warnings, labels or instructions of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the products involved significant dangers not readily obvious to the ordinary user of the products. BARD and DAVOL failed to warn of the known or knowable injuries associated with malfunction of the Composix Kugel Patch, including but not limited to rupture of the Patch and severe peritonitis and infection which would require subsequent surgical procedures and could result in severe injuries.

80. The dangerous and defective conditions in the Composix Kugel Patches existed at the time they were delivered by the manufacturer to the distributor. At the time Mr. THORPE had his hernia repair surgery the Composix Kugel Patch was in the same condition as when manufactured, distributed and sold.

81. Mr. THORPE did not know at the time of use of the Composix Kugel Patch, not at any time prior thereto, of the existence of the defects in the Patches.

82. Mr. THORPE suffered the aforementioned injuries and damages as a direct result of

DAVOL and BARD's failure to warn.

83. The conduct of BARD and DAVOL in continuing to market, promote, sell and distribute the Composix Kugel Patch after obtaining knowledge that the products were failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter BARD, DAVOL and others from similar conduct.

Wherefore, Plaintiffs respectfully request judgment in their favor and against DAVOL and BARD for such amount that is determined to be fair and reasonable, for such other relief as may be fair and reasonable under the circumstances and for their costs.

COUNT VII
Fraud

84. Plaintiffs re-allege and incorporate by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

85. In the course of business, DAVOL and BARD designed, manufactured and sold the Composix Kugel Patch for hernia repair surgeries.

86. At the time of the design, manufacture and sale of the Composix Kugel Patch, and more specifically at the time Mr. THORPE received the Composix Kugel Patch, they were defective and unreasonably dangerous when put to their intended and reasonably anticipated use. Further the Composix Kugel Patches were not accompanied by proper warnings regarding significant adverse consequences associated with the Composix Kugel Patch.

87. BARD and DAVOL was aware of the dangerous and defective condition of the products and intentionally withheld this information from Mr. THORPE, Plaintiff's physicians, and

the general public even though these significant dangers were not readily obvious to the ordinary user of the products, even after a post surgical complication had arisen.

88. BARD and DAVOL fraudulently presented to Plaintiffs, Mr. THORPE's physicians, and the general public that the Kugel Patch was a safe and effective product while they were fully aware that the dangerous and defective nature of the Kugel could and would cause injuries such as those suffered by Plaintiff.

89. Plaintiffs and Mr. THORPE's physicians relied upon the fraudulent misrepresentations and concealments of Defendants and allowed for the defective Kugel Patch to be implanted.

90. As a direct and proximate result of Plaintiffs' reliance on BARD's and DAVOL's fraudulent misrepresentations and concealments, Mr. THORPE was seriously and permanently injured.

91. The conduct of BARD and DAVOL in continuing to fraudulently market, promote, sell and distribute the Composix Kugel Patch while fraudulently concealing knowledge that the products were failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter BARD, DAVOL and others from similar conduct.

Wherefore, Plaintiffs respectfully request judgment in their favor and against DAVOL and BARD for such amount that is determined to be fair and reasonable, for such other relief as may be fair and reasonable under the circumstances and for their costs.

COUNT VIII
Misrepresentation by Omission

92. Plaintiffs re-allege and incorporate by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

93. Defendants misrepresented the mechanical soundness and reliability of the Kugel Composix Hernia Patches to the general public through promotional and marketing campaigns. Defendants continued this misrepresentation for an extended period of time, without disclosing material information regarding the defective, hazardous, and harmful complications relating to the Kugel Composix Hernia Patches.

94. Defendants took advantage of the limited ability Plaintiffs had to discover Defendants' strategic and intentional concealment of the defects in their Kugel Composix Hernia Patches.

95. Defendants concealed these design and/or manufacturing defects from the public by withholding information pertaining to the inherent design and/or manufacturing defects and high risks of failure relating to the Kugel Composix Hernia Patches, and presenting the devices as sound and reliable.

96. Defendants' intentional misrepresentations and omissions were made willfully, wantonly or recklessly to Plaintiffs, the public at large, and Plaintiff's surgeons to induce the purchase of Defendants' Kugel Composix Hernia Patch over other hernia mesh repair systems on the market.

97. Defendants knew or should have known of the high risk the Plaintiffs would encounter by unknowingly agreeing to have implanted one of Defendants' defectively designed and/or manufactured Kugel Composix Hernia Patches.

Wherefore, Plaintiffs respectfully request a judgment against DAVOL and BARD for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT IX
Loss of Consortium

98. Plaintiffs re-allege and incorporate by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

99. As a direct and proximate result of the Defendants' said negligence and conduct as detailed above and herein, Plaintiff, LAURE THORPE was caused to lose the consortium and society of the Plaintiff's spouse, Mr. THORPE.

Wherefore, Plaintiffs respectfully request judgment in their favor and against DAVOL and BARD for such amount that is determined to be fair and reasonable, for such other relief as may be fair and reasonable under the circumstances and for their costs.

PLAINTIFFS REQUEST A TRIAL BY JURY ON ALL COUNTS.

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LAURE THORPE
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